

## **REMARKS/ARGUMENTS**

### **THE INVENTION**

This invention provides for a novel method of treating postpartum psychosis using a glucocorticoid receptor antagonist (GRA). Before this invention, there was no report that postpartum psychosis was due to a glucocorticoid regulatory dysfunction and treatable with GRAs.

### **INTERVIEW**

Pursuant to Rule 133(b), applicant acknowledges the telephone interview of June 11, 2008. During the interview, the Examiner Packard explained that his primary concern was over claim scope. The pending claims were read to "treat symptoms" when the disclosure treats "psychotic" symptoms of patients having postpartum psychosis. Applicant stated that this concern should be addressed by a minor amendment to the claims. Examiner Packard agreed and stated that he would consider any amendment submitted by the applicant.

### **STATUS OF CLAIMS**

Claims 1-11 and 15 are pending. All claims have been rejected as obvious over prior art. Claim 1 has been amended to expressly state that the symptom being treated is the psychosis of patient's having postpartum psychosis. Express support of the added material is found in the original claim 1 which recited, "first psychotic symptoms" at line 4 and at ¶ 7 disclosing the treatment of "psychotic symptoms."

REJECTION UNDER §103(a)

Claims 1-6, 9[8]-11 and 15 were rejected as obvious in view of Schatzberg and Stowe. Schatzberg describes treating the psychotic feature of psychotic major depression with glucocorticoid receptor antagonists [GRAs] and Stowe describes postpartum psychosis.

The Examiner appears to have understood that the cited prior art of Schatzberg relates to treating the psychotic symptoms of patients having psychotic major depression and that the patient population being treated in the pending claims, mothers with postpartum psychosis, are patentably distinct from patients suffering from psychotic major depression. However, the Examiner was clearly of the opinion that the grammar of the original claims permitted them to read too close to the prior art. The Examiner wrote:

In response to applicant's argument that the references fail to show certain features of the invention, it is noted that the features upon which the applicant relies (i.e. treating postpartum psychosis) are not recited in the rejected claim(s)... Specifically, the claims are directed to ameliorating "the symptoms" of postpartum psychosis... the population which exhibit symptoms of postpartum psychosis is much broader.

Although applicant disagrees that the scope of the original claims read beyond mothers suffering from postpartum psychosis, appropriate claim amendments have been introduced into claim 1 that are believed to more expressly limit the claim scope to treating the psychosis of mothers suffering from postpartum psychosis. Should the Examiner disagree, he is respectfully asked to call the undersigned attorney and explore alternative language that might be satisfactory.

Claim 7 reciting specific GRAs was rejected under Schatzberg and Stowe in view of Bradley disclosing specific GRAs. Claim 7 depends from claim 1. Presuming the amendments to claim 1 overcome the Examiner's concerns, claim 7 will also be patentable.

At page 4 of the outstanding Final Office Action, the wrote in his concluding remarks:

It would have been obvious to one of ordinary skill in the art to use the specific GRAs to treat the symptoms of postpartum psychosis when the condition shows the same initial symptoms of postpartum depression.

During the interview, this passage was briefly discussed. Applicant requested clarification because the statement presumes:

(i) that the prior art taught treatment of postpartum depression with GRAs;

(ii) that symptoms of postpartum depression preceded postpartum psychosis; and,

therefore it would be obvious to treat both disorders with GRAs.

It was pointed out that the prior art did not teach that either of these two premises were true. Postpartum depression is not known to be treatable by GRAs. Medical treatises clearly indicate that postpartum depression and postpartum psychosis are distinct clinical disorders of unknown etiology. Finally, postpartum psychosis is not necessarily preceded by postpartum depression (see Response dated Feb. 13, 2008; Exhibit 7 @ page 2).

It was understood that this paragraph was miswritten and was intended to re-address the psychotic major depression of Schatzberg. The June 11th interview then focused on the cited prior art.

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Examining Group 1612

PATENT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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